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JF W

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# TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/505,317
Filing Date	
First Named Inventor	Tina Rademacher
Art Unit	1615
Examiner Name	
Attorney Docket Number	R00861US - 90568

Total Number of Pages in This Submission

## ENCLOSURES (Check all that apply)

<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to TC
<input checked="" type="checkbox"/> Fee Attached (\$130.00)	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> (CREDIT CARD FORM) Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Post card receipt
<input checked="" type="checkbox"/> Information Disclosure Statement (SUPPLEMENTAL)	<input type="checkbox"/> Request for Refund	Ltr re erroneous issuance of
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	Filing Rcpt; Combined Dec. &
<input type="checkbox"/> Reply to Missing Parts/Incomplete Application	<input type="checkbox"/> Landscape Table on CD	P/A w/fee; Ltr w/IPER in English
<input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	Remarks	

Please charge any additional fees or credit any overpayment to applicant's attorney's Deposit Account No. 08-2441.

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature			
Printed name	D. Peter Hochberg		
Date	4 / 20 / 2005	Reg. No.	24,603

## CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	
Typed or printed name	Christine Kotran
Date	4 / 20 / 2005

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



Effective on 12/08/2004.

Fee pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FEE TRANSMITTAL**  
**For FY 2005**☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$)

**Complete if Known**

Application Number	10/505,317
Filing Date	
First Named Inventor	TINA RADEMACHER
Examiner Name	
Art Unit	1615
Attorney Docket No.	R00861US - 90568

**METHOD OF PAYMENT (check all that apply)**

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_  
☒ Deposit Account Deposit Account Number: 08-2441 Deposit Account Name: D. Peter Hochberg Co., PA

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 or, for Reissues, each claim over 20 and more than in the original patent	50	25
Each independent claim over 3 or, for Reissues, each independent claim more than in the original patent	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)	Multiple Dependent Claims	Fee (\$)	Fee Paid (\$)
- 20 or HP =	x	=				

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
- 3 or HP =	x	=	

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
- 100 =	/ 50 =	(round up to a whole number) x		

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

Other: LATE FILING OF DECLARATION (FEE CODE 1051)

Fees Paid (\$)

130.00

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	24,603	Telephone	216-771-3800
Name (Print/Type)	D. Peter Hochberg	Date	4/20 / 2005		

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Tina Rademacher et al.  
Serial No. : 10/505,317 / Conf. No. 5171  
Filed : I.A. date: 02/04/2003 / Priority date: 02/21/2002  
Title : FILM-SHAPED OR WAFER-SHAPED PHARMACEUTICAL  
PREPARATION WITH MASKED TASTE (**per Prelim. Amd.  
mld. 8/20/2004**)  
Examiner : \_\_\_\_\_ / Art Unit : 1615  
Attorney Docket: RO0861US (#90568)

**LETTER**

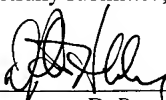
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Enclosed for the records of the USPTO is a copy of the English translation of the International Preliminary Examination Report for PCT/EP2003/001052.

Respectfully submitted,

DPH/SM/ck  
Enc.

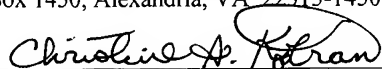
By:   
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Reg. No. 24,603

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1940 East Sixth Street - 6<sup>th</sup> Floor  
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**CERTIFICATE OF MAILING UNDER 37 CFR 1.8(a)**

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Date: April 20, 2005

  
Christine A. Kotran

Translation

PATENT COOPERATION TREATY

PCT/EP2003/00105



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference LTS 2002/001 PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/001052	International filing date (day/month/year) 04 February 2003 (04.02.2003)	Priority date (day/month/year) 21 February 2002 (21.02.2002)
International Patent Classification (IPC) or national classification and IPC A61K 9/70		
Applicant LTS LOHMANN THERAPIE-SYSTEME AG		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>7</u> sheets.</p>
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the report</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>

Date of submission of the demand 08 May 2003 (08.05.2003)	Date of completion of this report 13 April 2004 (13.04.2004)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/EP2003/001052

## I. Basis of the report

1. This report has been drawn on the basis of *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.)*:

- ☐ the international application as originally filed.
- ☒ the description, pages 1-19, as originally filed,  
 pages \_\_\_\_\_, filed with the demand,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☒ the claims, Nos. \_\_\_\_\_, as originally filed,  
 Nos. \_\_\_\_\_, as amended under Article 19,  
 Nos. \_\_\_\_\_, filed with the demand,  
 Nos. 1-26, filed with the letter of 27 September 2003 (27.09.2003),  
 Nos. \_\_\_\_\_, filed with the letter of \_\_\_\_\_.
- ☐ the drawings, sheets/fig \_\_\_\_\_, as originally filed,  
 sheets/fig \_\_\_\_\_, filed with the demand,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_,  
 sheets/fig \_\_\_\_\_, filed with the letter of \_\_\_\_\_.

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/EP 03/01052

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Non-establishment of opinion with regard to novelty,  
inventive step and industrial applicability

Claims 22-26 relate to subject matter which this Authority  
considers to fall under PCT Rule 67.1(iv). Consequently,  
no opinion is established with regard to the industrial  
applicability of the subject matter of these claims  
(PCT Article 34(4)(a)(i)).

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/EP 03/01052

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

## 1. Statement

Novelty (N)	Claims	15, 16, 18	YES
	Claims	1-14, 17, 19-26	NO
Inventive step (IS)	Claims		YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims		NO

## 2. Citations and explanations

1. Reference is made to the following document:

D1: US-A-2001/0006677.

2. Novelty (PCT Article 33(2))

The present application does not comply with the requirements of PCT Article 33(2), because the subject matter of claims 1-14, 17 and 19-26 is not novel.

Film or wafer-type effervescent medicinal preparations are already known from D1 (see D1, columns 51, 56, 57 and 85, and the examples). It is clear from the dependent claims of the present application, as well from the scope of claim 1, that the "gas-forming component" could be an effervescent mixture.

The subject matter of claims 1-14, 17 and 19-26 is therefore novel.

3. Inventive step (PCT Article 33(3))

Document D1 can be considered to be of particular relevance as regards inventive step (PCT Article 33(3)). That document in fact solves the same problem as the present

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/EP 03/01052

application. The subject matter of claims 15 and 18 cannot be considered to be inventive.

Consequently, so far as novel subjects as per the invention are affected, the present application obviously does not comply with the requirements of PCT Article 33(3) in relation to that document, which discloses the prior art.

4. The PCT Contracting States do not have uniform criteria for assessing the industrial applicability of claims 22-26 in their present form. Patentability may also depend on the wording of the claims. The EPO, for example, does not recognize the industrial applicability of claims to the medical use of a compound; it may, however, allow claims to the first medical application of a known compound or to the use of such a compound in the manufacture of a drug for a new medical application.